INVESTIGATIONAL AGENT AUDIT CHECKLIST

Drug name(s):	
Protocol #	Protocol Version
Audit Interval	
Study coordinator/data manaç	ger:
Lead Pharmacist (if applicable	e):
Date of Last Audit (if applicab	le):
Accountability records:	
Electronic records	
Paper records	
Mixed records (paper and elect	tronic)
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	Υ	Z	N/A	Comments
Drug Acquisition				
Drug receipts are signed and dated. Shipping records				
maintained in the study binder/file.				
Lot number and expiration date are recorded on receipts. If				
expiration date is not available, "unknown" is inserted. Lot				
number should not be "unknown".				

	Υ	N	N/A	Comments
Manufacturer and supplier for all IP receipts is recorded on				
the Drug Accountability Record Form (DARF).				
Confirm temperature device data downloaded and report				
printed for all receipts, if applicable.				
Drug arrival confirmed with sponsor, if applicable (with				
receipt of confirmation).				
Drug Accountability Record Form (DARF)-Compliance with	h P	rote	ocol R	equirements
For National Cancer Institute (NCI)-supplied agents, NCI				
DARF is utilized. For non-NCI-supplied drugs, NCI DARF,				
sponsor DARF, or sponsor approved DARF is used. Check				
protocol/study documents and communication with sponsor				
to ensure that correct DARF/DARF version is used (the form				
did not expire).				
When NCI DARFs are used, ORAL NCI Investigational Agent DARF is used for all oral drugs.				
For NCI-supplied agents, if electronic DARFs are used				
instead of the NCI DARF, the eDARF printout is identical to				
the NCI DARF.				
For NCI-supplied agents, DARFs are not lot-specific (i.e., all				
lots are listed on same page).				
For NCI-supplied agents, for each shipment, the investigator				
listed on the shipping receipt is the same as the investigator				
listed on the DARF, and only one investigator is listed on				
each DARF.				
Patient-specific DARF is used, if required by protocol.				
Separate DARF is used for each study agent or placebo and				
each study protocol.				
Separate DARF is used for each study agent strength and				
dosage form, if applicable.				
If applicable, drug assignment (with appropriate				
documentation) for a blinded trial complies with the				
procedure described in the protocol/study documents.	<u> </u>			
Drug Accountability Record Form (DARF)-Central Location	n	l	Ι	
Recordings on the DARF are maintained in a timely manner. DARF header/footer is properly and completely filled out (no				
blanks). (e.g., drug name, strength, lot number(s), expiration				
date if available, page number, etc.). Drug name matches IP				
receipt.				
If expiration date is not available, "unknown" is inserted.				
Drug dispensing unit and strength are recorded, if				
applicable.				
Balance forward is completed.				
Subject initials (not name) and subject study number (not				
medical record number) are recorded on DARF.				
Date and quantity of drug receipt are correctly recorded on				
DARF.				
Date and quantity drug dispensed are correctly recorded on				
DARF.				
Date, quantity and lot number of drug transported to a				
satellite are correctly recorded on DARF, if applicable.				
Date, quantity and lot number of unused drug returned				
from a satellite are correctly recorded on DARF, if				
applicable.			<u> </u>	

	Υ	N	N/A	Comments
Date and quantity of drug destroyed/transferred to				
another study or another institution/returned are				
correctly recorded on DARF and documentation is available				
for review, if needed.				
Only one dose dispensed is recorded for individual subjects				
on each line entry.				
Number of units used for compounded preparations is				
appropriate for the dose.				
The inventory balance for each line on the DARF is correct				
(i.e., math).				
Corrections made with single line strike through, dated and				
initialed (no erasures and whiteouts) with black or blue ink.				
No ditto marks.				
All entries are initialed and dated.				
All entries are dated in chronological order. If date is not in				
sequential order, there is a note to file or comments with an				
explanation.				
Actual drug inventory matches drug accountability record.				
Drug Accountability Record Form (DARF)-Satellite Location	on (Fill	if a sa	itellite is used. Duplicate
this section if more than one satellite is used).				
Recordings on the DARF are maintained in a timely manner.				
DARF header/footer is properly and completely filled out (no				
blanks). (e.g., drug name, strength, lot number(s), expiration				
date if available, page numbers, etc.). Drug name matches				
IP receipt.				
If expiration date is not available, "unknown" is inserted.				
Drug dispensing unit and strength are recorded, if				
applicable.				
Balance forward is completed.				
Subject initials (not name) and subject study number (not				
medical record number) are recorded on DARF				
Date, quantity and lot number of drug received from central				
location are correctly recorded on DARF.				
Date, quantity and lot number of unused drug returned to a				
central location from a satellite are correctly recorded on				
DARF.				
Date and quantity of drug dispensed are correctly recorded				
on DARF.				
Only one dose dispensed is recorded for individual subjects				
on each line entry.				
Number of units used for compounded preparations is				
appropriate for the dose.				
The inventory balance for each line on log is correct (i.e.,				
math).				
Corrections made with single line strike through, dated and				
initialed (no erasures and whiteouts). No ditto marks.				
All entries are initialed and dated.				
All entries are dated in chronological order. If date is not in				
sequential order, there is a note to file or comments with an				
explanation. Actual drug inventory matches drug accountability record.				
Actual drug inventory matches drug accountability record.]		<u> </u>	

Drug Transfers/Transports		
If drug is transferred to another protocol, transfer must be		
approved by CTEP or study sponsor in advance,		
documentation must be available. For NCI-supplied agent,		
NCI Transfer Investigational Agent Form must be used.		
If drug transferred to another site, transfer must be		
approved by CTEP or study sponsor in advance,		
documentation available.		
If NCI-supplied agent was transported or transferred to other		
investigators or locations, it was <u>not</u> repackaged or		
reshipped by mail or express carrier.		
Drug Return / Destruction		T
Oral agents returned from subjects documented on the		
same oral agents DARF that lists the dispensing		
(recommended).		
Returned drug from subjects is available for review if		
specified by the sponsor. If used drug was returned to		
sponsor/destroyed on site, documentation is available.		
For NCI-supplied agents, expired drug is returned/destroyed		
within 90 calendar days of expiration. Drug		
return/destruction document available.		
For NCI-supplied agents, if the study is closed, unused/un-		
dispensed drug is returned/destroyed per protocol 90		
calendar days after the close date.		
For NCI-supplied agents, documentation of NCI approval of		
the destruction on site and all communication with the NCI is		
available.		
If drug is destroyed, there is a local site destruction policy		
available.		
Storage and Security		
Drugs are physically stored separately by protocol in		
container labeled with drug name and protocol number.		
Drugs are separated by strength and dosage form. For NCI-		
supplied drug the agents need to be stored by ordering or		
designated ordering investigator.		
Drugs are stored under proper conditions (refrigeration,		
freezer and room temperature).		
Temperatures at the storage area are documented and		
monitored.		
If there was a temperature excursion, there is		
documentation of correspondence that the study sponsor		
was contacted, if applicable.		
If there was a temperature excursion, the drug was		
quarantined, if applicable.		
Drug stored in secured and limited access area.		
Prescriptions		
Prescriptions/orders are signed by authorized prescribers.		
For NCI-supplied agents, the investigator prescribing or co-		
signing must have an active registration status as either		
Prescribing Investigator (IVR) or Nonphysician Investigator		
(NPIVR) in the CTEP Registration and Credential		
Repository (RCR).		
Patient Specific Reviews The correct study agent (correct protect) number, correct		
The correct study agent (correct protocol number, correct		
study supply) was dispensed to the patient.		<u> </u>

Only study supplied drug is dispensed and recorded on		
DARF. Commercial drug is not substituted for study		
provided drug. Study agents cannot be borrowed.		
For oral drugs or drugs dispensed for home administration		
doses and start/end dates listed on the Case Report Form		
(or equivalent) match the drug accountability records.		
For drugs administered in the clinic, doses and dates		
provided on the Case Report Form (or equivalent) match the		
drug accountability records.		
Study drug is only dispensed to subjects who are registered		
to the study.		

General Suggestions:

- If applicable, un-blinding performed by pharmacy or other study personnel is documented.
- ➤ Patient list (Master Log) is available and up-to-date, especially for sites using paper records. Same patient initials and study number used on master log and dispensing record.
- > Investigational agent handling and dispensing instructions available.
- > All materials organized neatly and easily accessible.
- > Most current version of the protocol that is approved by IRB is available and has been reviewed.
- Most current version of site SOPs (e.g. destruction, returns, transfer/transport) are available.
- > Ensure that pharmacy training logs are complete and up to date with the most recent IRB-approved protocol.

Additional Comments:

Prepared by:		I	
	Name	Date	
Reviewed by (pharr	nacist/study staff):		1
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Resources:

- NCI Pharmacy Audit Worksheet http://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Pharmacy Audit Worksheet.pdf (Last accessed 23Dec2024)

Acknowledgements:

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- Virginia Mason Medical Center Investigational Drugs Services

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